FISH.
FISH & RICHARDSON

REDACTED – FOR PUBLIC INSPECTION

Fish & Richardson P.C.
1000 Maine Avenue, S.W.
Suite 1000
Washington, DC 20024

202 783 5070 main
202 783 2331 fax

VIA HAND DELIVERY AND ELECTRONIC FILING

Terry G. Mahn
Principal
mahn@fr.com
202 626 6421 direct

December 26, 2018

Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th St. SW
Washington, D.C. 20554

Re: Request for Confidential Treatment
Petition to Modify Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices

Dear Ms. Dortch:

Pursuant to Section 1.3 of the rules of the Federal Communications Commission ("Commission"), Zoll Medical Israel Ltd. (successor in interest to Kyma Medical Technologies, Ltd. ("Zoll")) hereby submits the attached confidential version of its Petition to Modify Waiver, the redacted version of which has been filed electronically.

Pursuant to Sections 0.457 and 0.459 of the Commission's rules, Zoll requests that the Commission afford confidential treatment to the information in the attached Petition that has been marked confidential, and withhold that information from public inspection. The Petition describes proprietary information related to ultra-wideband medical diagnostic technology for use by congestive heart failure patients. Disclosure of the commercially sensitive information in this Petition would have a negative competitive impact on Zoll. Such information falls within Exemption 4 of the Freedom of Information Act ("FOIA"),[1] as well as the Commission's rule[2] describing information not routinely made available for public inspection, and thus should be appropriately protected.

In support of this request and pursuant to Section 0.459(b) of the Commission's rules, Zoll hereby states as follows:

1. Identification of the specific information for which confidential treatment is sought.

Zoll requests confidential treatment with respect to confidential information redacted from the version of the Petition filed electronically with the Commission.

[1] 5 U.S.C. § 552(b)(4).
[2] 47 C.F.R. § 0.457(d).

2. Identification of the Commission proceeding in which the information was submitted or a description of the circumstances giving rise to the submission.

Zoll submits this information with respect to a petition to modify an earlier Part 15 waiver granted by the Commission.

3. Explanation of the degree to which the information is commercial or financial, or contains a trade secret or is privileged.

The information redacted in the attached Petition contains confidential information, internal to the company, about an ultra-wideband medical device currently under development. This information is not required for an equipment certification and thus, will not be made publicly available at any time.

4. Explanation of the degree to which the information concerns a service that is subject to competition.

The confidential information involves ultra-wideband medical diagnostic technology for use by congestive heart failure patients. This is a highly competitive commercial market and the information redacted could be harmful to Zoll.

5. Explanation of how disclosure of the information could result in substantial competitive harm.

Disclosure of the information included in the Petition could cause substantial competitive harm by providing competitors with information that could be used against Zoll in the market.

6. Identification of any measures taken by the submitting party to prevent unauthorized disclosure.

The information will be kept confidential with the company and will not be publicly available.

7. Identification of whether the information is available to the public and the extent of any previous disclosure of the information to third parties.

The information is not available to the public and has not been previously disclosed to third parties except pursuant to non-disclosure agreements.

8. Justification of the period during which the submitting party asserts that material should not be available for public disclosure.

Zoll requests that the information identified in the Petition be treated as confidential indefinitely.

9. Any other information that the party seeking confidential treatment believes may be useful in assessing whether its request for confidentiality should be granted.

Zoll has nothing further to add.

If a request for disclosure occurs, please provide sufficient advance notice to the undersigned prior to any such disclosure to allow Zoll to pursue appropriate remedies to preserve the confidentiality of the information.

Respectfully submitted,

By: */s/ Terry G. Mahn*

Terry G. Mahn

Fish & Richardson P.C.
1000 Maine Avenue S.W.
Suite 1000
Washington, D.C. 20024
(202) 783-5070

Counsel to Zoll Medical Israel Ltd.

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)
	)
Zoll Medical Israel Ltd. (successor in	)
interest to Kyma Medical Technologies, Ltd.)	)
	)
Waiver of Part 15 of the Commission's Rules	)
Applicable to Ultra-Wideband Devices	)

To: Chief, Office of Engineering and Technology

Petition to Modify Part 15 Rule Waiver

On September 6, 2016, the Commission granted a request by Kyma Medical Technologies Ltd. (since acquired and re-named Zoll Medical Israel Ltd. ("Zoll")), for a waiver of various Part 15 rules governing unlicensed ultra-wideband ("UWB") devices, to permit the certification and marketing of its medical imaging and diagnostic device, the uCor 3.0 ("uCor").[1] The uCor is designed to monitor patients suffering from congestive heart failure (CHF).

Several parties submitted comments on Kyma's waiver request.[2] After due consideration, the Commission found that the uCor device posed no greater risk of causing harmful interference to communication services than UWB devices already permitted under the existing rules. Accordingly, the Commission issued rule waivers for: (1) the "at any point in time" requirement

[1] *Kyma Medical Technologies Ltd. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, ET Docket No. 15-119, Order, 31 FCC Rcd 9705 (2016) ("*Kyma Order*"); *see also* 47 C.F.R §§ 15.503(d), 15.513(a), 15.521(d), 15.525.

[2] *See* Comments of The GPS Innovation Alliance, ET Docket No. 15-119 (filed June 19, 2015); Comments of the National Public Safety Telecommunications Council, ET Docket No. 15-119 (filed June 19, 2015); and Comments of Robert Bosch, LLC, ET Docket No. 15-119 (filed June 19, 2015).

of Section 15.503(d); (2) the measurement requirements in Sections 15.31(c) and 15.521(d) that require the transmitter stepping function be stopped; (3) the spectrum requirements in Section 15.513(a) which limit the operation of UWB medical devices to the 3.1 GHz-10.6 GHz band; and (4) the agency coordination requirement in Section 15.525 for UWB devices. In addition, the following waiver conditions were imposed:

- The uCor device would have to be certified by an authorized Telecommunications Certification Body.
- The uCor device would be operated with stepped frequency modulation in approximately 25 MHz steps between 530 MHz and 2105 MHz.
- The uCor device dwell time on any one frequency would not exceed 100 μs in any 20 msec period.
- Measurements of emissions from the uCor device could be conducted with the stepping function active.
- The UWB operations were to be limited to body imaging measurement functions.
- The uCor device could not transmit data using UWB techniques.
- Measurements of emissions from the uCor could be conducted using a phantom body as described in the FCC certification for the previously approved device (FCC ID: 2ABHFUCOR100).
- The uCor device would be enabled to transmit only when the patient is actively being monitored.
- The uCor would cease transmissions when not in contact with the human body.
- The uCor would be used under the direction of a healthcare professional.
- The uCor device would be required to show compliance with all other technical and operational requirements applicable to UWB medical imaging devices under Part 15, Subpart F of the Commission's rules.
- The uCor device would not operate more than 8 times per day, each time for a duration not to exceed 60 seconds.

- Kyma would be required to notify both health care providers and patients, by clear and prominent instruction in the uCor users' manual that the uCor device should be turned off on aircraft.

Pursuant to these waiver conditions, an equipment certification for the uCor was granted on March 23, 2017.[3]

Since then, the uCor has undergone careful study on its safety and effectiveness on a broad cross-section of CHF patients. **[***BEGIN CONFIDENTIAL***]** [redacted] **[***END CONFIDENTIAL***]** In all other respects, the modified device is technically and operationally identical to the waivered device.

On September 5, 2018, Zoll received an experimental license from the Commission to conduct clinical trials using the modified device.[4] Those trials are proving very successful, and Zoll now desires to commercialize the modified uCor for use by these patients. Because the modification, albeit minor in terms of its spectrum impact, does not meet the strict waiver conditions, Zoll hereby requests the Chief of the Office of Engineering and Technology ("OET") grant this Petition under its general delegation of authority.[5] To speed up the process, Zoll further requests that the Petition not be put on public notice so that it and the Commission will be spared the unnecessary and repetitious industry objections that accompany all such UWB waiver requests.

[3] FCC ID: 2ABHFUCOR30.
[4] *See* Zoll Medical Corporation, Call Sign WJ2XRR; File No. 0568-EX-CN-2018 (granted Sept. 5, 2018).
[5] *See* 47 C.F.R. § 0.241.

The Original Waiver Conditions were based on the uCor's Design and not on any Specific Spectrum Protection Standards

The Commission waived its Part 15 Rules on the basis that the uCor posed no greater risk of causing harmful interference to communication services than various UWB devices that had already been permitted. The Commission noted that stepped frequency devices that transmit sequentially over a large band of spectrum had previously been approved under the UWB rules and were allowed to be tested with their stepping function active;[6] that the spectrum used by the uCor would be the same as permitted for ubiquitous UWB ground penetrating radar and wall imaging devices;[7] and that no agency coordination would be needed for devices that are not used outdoors for extended periods of time.[8]

The Commission also observed that the uCor's inherent operating conditions would ensure that it would not threaten harmful interference to spectrum licensees. For example, it was noted that the uCor would only be used under the direction of a healthcare professional, thereby limiting the number of devices in operation at any given time, and it would only be used in contact with or in close proximity to the human body for the purpose of detecting fluid levels, thereby directing all of its low energy transmissions into the body cavity where it would be absorbed.

To ensure that the uCor would not transmit "indefinitely" on any individual frequency step (25 MHz), the Commission conditioned the waiver on the specific transmission protocols described in the waiver request – in other words, on the chosen technical characteristic of the

[6] *See, e.g., Curtiss-Wright Controls, Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices,* ET Docket No. 10-167, Order, 27 FCC Rcd 234 (2012).
[7] *See* 47 C.F.R. § 15.509.
[8] *See Kyma Order* at ¶ 19.

original uCor design, as opposed to any particular interference protection standard.[9] Although concerns were raised as to the possibility of concentrated transmissions from multiple devices, the Commission found it "extremely unlikely" that more than one co-located device would transmit on the same frequency at the same time. In addition, because the device was designed to transmit only when a patient is being monitored, the likelihood of simultaneous emissions was further reduced. Accordingly, the Commission determined that there was "negligible potential" for harmful interference to incumbent spectrum users (specifically, public safety land mobile users), that additional constraints beyond those already designed into the system were unwarranted, and that there was no compelling need to add further complexity and cost to the uCor device.[10]

[*BEGIN CONFIDENTIAL***]** [redacted] **[***END CONFIDENTIAL***]** Indeed, as compared to other UWB devices operating in the same spectrum, the uCor is relatively benign. It is a fixed indoor device with no mobile use, cannot be operated continuously and is required to be operated under professional supervision. Collectively, these operating parameters provide, in the words of the Commission, "negligible potential" for causing harmful interference to spectrum licensees.

[9] *Id.* at ¶ 22.
[10] *Id.* at ¶ 30.

The [*BEGIN CONFIDENTIAL***] [redacted] [***END CONFIDENTIAL***]**
Modification does not involve a Rule Waiver

The modified uCor does not require any change in the rule waivers that were granted by the Commission. It will continue to comply with the *Order* as applied to Sections 15.503(d), 15.31(c), 15.521(d), 15.531(a) and 15.525 of the rules. **[***BEGIN CONFIDENTIAL***]** [redacted] **[***END CONFIDENTIAL***]** In any event, the improvement in diagnostic efficacy for the

[11] [redacted]

larger population of CHF patients clearly and unmistakably outweighs the insignificant risks of spectrum interference. Accordingly, the Commission should approve this minor but important modification to the uCor device.

This Petition should be granted by the Chief Engineer under Delegated Authority

The Commission has analyzed and granted previous waivers for UWB devices that use stepped frequency modulation, operate over at least 500 MHz of spectrum, and are tested with the stepping function active.[12] In each case, the Commission also imposed various operating conditions that tracked the technical features of the device, thereby rendering each waiver unique to a particular device. Thus, if one or more of the conditioned technical features were to change, even minimally, the waiver conditions could not be met and the device manufacturer would be required to seek Commission approval to implement the change.

This is the situation now faced by Zoll, where a minor, evolutionary technical change to the uCor device falls outside the strict requirements set forth in the *Order* and, therefore, must be approved by the Commission. However, it cannot be an efficient expenditure of Commission resources to review and approve all the minor technical changes that are made to waivered devices, particularly where it is evident that they have little or no impact on the interference concerns addressed in the waiver grant. Instead, it makes more sense for these changes to be handled by the OET Chief under its general delegation of authority.

[12] *See Curtiss-Wright Controls, Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, ET Docket No. 10-167, Order, 27 FCC Rcd 234 (2012); *Petition for Waiver of the Part 15 UWB Regulations Filed by Multi-band OFDM Alliance Special Interest Group*, ET Docket No. 04-352, Third Memorandum Opinion and Order and Memorandum Opinion and Order, 25 FCC Rcd 11390 (2010); *Proceq USA Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, Order, DA 18-251 (rel. March 14, 2018).

Section 0.241 of the Commission's rules sets forth the scope of the OET Chief's authority to act on behalf of the Commission, which includes the administration of the Part 2 and Part 15 rules, along with the equipment authorization program. The OET Chief is required to refer waiver requests to the Commission *en banc* only when such requests "contain new or novel arguments not previously considered by the Commission or present facts or arguments which appear to justify a change in Commission policy." Here, there are no new or novel facts or arguments that involve a change in Commission policy; rather, the change is to an operating parameter that was simply part of the original product design.

Indeed, the only new "fact" raised in this Petition is a minor change to **[***BEGIN CONFIDENTIAL***]** [redacted] **[***END CONFIDENTIAL***]** Zoll has tested the modified device in accordance with the Commission's rules and measurement procedures (per the waiver) and can confirm that it complies fully with Part 15 Subpart F requirements and shows identical test results to the original uCor device. Thus, there would appear to be no public interest served in soliciting comments on the duty cycle modification requested in this Petition. A public notice will serve only to delay the approval and marketing of a device that is needed by CHF patients as the usual industry "watch dogs" file repetitive and threadbare objections to all such waiver requests.

Conclusion

Based on the foregoing, Zoll respectfully requests a grant of this Petition by the Chief of OET to serve the public interest.

Respectfully submitted,

By: */s/ Terry* G. *Mahn*

Terry G. Mahn

Fish & Richardson P.C.
1000 Maine Avenue S.W.
Suite 1000
Washington, D.C. 20024
(202) 783-5070

Counsel to Zoll Medical Israel Ltd.

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